# I. Clinic Management & Operations

# a. Clinic Set Up

Consider federal, state, and local guidance when establishing measures (such as inventory management, appropriate PPE, hand hygiene, social distancing, etc.) to protect clinic staff and patients. Overall guidance for Vaccination Clinic Location and Layout from the CDC can be found <a href="here">here</a>.

- 1. Set up your clinic in a well-ventilated facility (e.g., large gymnasium) or space that can hold the maximum number of individuals expected at a time and follow the recommended current phase guidelines issued by the Governor (physically distanced at least 6 feet apart with masks [also known as cloth face coverings]).
- 2. Regardless of the site type (e.g., walk-through, curbside, drive-through, or mobile clinic), temporary locations must have sufficient capability to accommodate physical distancing, inventory management, and appropriate personal protective equipment (PPE) for staff and masks for patients.
- 3. Clinic locations and processes that were successful in previous years might not be appropriate during the COVID-19 pandemic because of the need for enhanced safety precautions. Even if the same space is used, it will likely need to be set up and function differently because of COVID-19 social distancing requirements.
- 4. Consider conducting appointment-only temporary clinics held in schools, churches, and pharmacies. Consider using large venues with multiple vaccination and waiting areas. Mark areas with 6 feet of spacing using circles or blocks. Seat household groups together.
- 5. <u>Curbside and drive-through clinics</u> may provide the best option for staff and patient safety during the COVID-19 pandemic. Consider having people wait for 15 or 30 minutes (depending on assessed health history) after vaccination in their cars in a separate parking lot that is monitored. Instruct them to activate their car's panic alarm or sound their horn for assistance. Cones with white boards in front of the cars may be used to indicate the time the vaccine was administered and estimated time the individual may be released.
- 6. For walk-through clinics, it's important to establish line queues that maintain separation between individuals or to ask individuals to wait in their vehicles or another location until called. Consider



use of a text message alert when it is the individual's time to come into the clinic. Clinic flow should be one way. Individual sites will have benefits and limitations, and site assessments will be required before use.

- 7. Refer to the Cybersecurity and Infrastructure Security Agency (CISA) <u>COVID-19 Vaccine</u>
  <u>Distribution Physical Security Measures Infographic</u> for a non-comprehensive list of proactive measures to enhance physical security.
- 8. It is always preferable to have vaccine(s) shipped directly to the clinic site instead of transporting them from another facility. Therefore, if possible, select a location with on-site equipment that can secure and store vaccines at appropriate temperatures. Plans must be in place to ensure staff can check the shipment immediately upon arrival to ensure there has been no temperature excursion, place the vaccines in storage unit(s), and regularly monitor vaccine temperatures.
- 9. Regardless of whether vaccines are delivered to the site or transported there, plans must include regular monitoring of vaccine temperature before, during, and after the clinic.
- 10. During the COVID-19 pandemic, physical distancing practices must be integrated into clinic flow and setup, including:
  - a. A screening station at the entrance for temperature checks (if required) and any screening questions for COVID-19.
  - b. Vaccination stations should be at least 6 feet apart, and clinic flow should be one way and allow maintenance of at least 6 feet between individuals, including in all waiting areas.
  - c. Signage, banners, and floor markers to instruct patients to wear masks, to remain 6 feet apart from other patients and clinic staff, and to move clinic flow in one direction.
  - d. Hard plastic barriers at patient contact areas, as appropriate, to provide barrier protection. Consider desks and counters at registration and screening areas to minimize contact.
  - e. Visual alerts such as signs and posters at entrances and in strategic places to provide instructions on hand hygiene, respiratory hygiene, and cough etiquette.
  - f. Signage or staff asking patients waiting to remain outside (e.g., stay in their vehicles, if applicable) until called in for their appointments, or set up triage booths to safely screen



patients and reduce crowding in waiting areas. Provide adequate covered space, taking weather into consideration, for those asked to wait outside.

11. At drive-by venues, adequate parking must be available so those receiving vaccines have a place to wait post-vaccination. Examples of optimal clinic set up below:



Gymnasium in Richmond



Salem Civic Center, Salem





Bus loop vaccination at a middle school in

Charlottesville





Three Rivers post vaccination parking area with timing for post-vaccination observation

#### b. Clinic Operations

- 1. Consider using online or phone options for scheduling appointments and completing paperwork, when possible. Such processes should include registration, obtaining insurance information (if needed), screening for contraindications and precautions, and texting or emailing vaccine immunization information statements (VIISs) or emergency use authorization (EUA) forms.
- 2. Have EUA fact sheets and consent forms (if applicable) ready in a convenient location to provide to patients prior to vaccine administration.
- 3. Confirm patients have not received any other vaccines in the past two weeks. CDC has recommended that no other vaccines be given 2 weeks before or after a COVID-19 vaccine.
- 4. Request patients coming in for the second dose bring their vaccination card and confirm with the patient which vaccine they received for their first dose and when.
- 5. Ensure all patients and accompanying attendants wear a mask that covers the nose and mouth. If a patient or attendant is not wearing a mask, they must be provided one. Note: Masks should not be placed on a child under 2 years of age, anyone who has trouble breathing, or anyone who is unconscious, incapacitated, or otherwise unable to remove the mask without assistance.
- 6. Cleanse and disinfect vaccination stations at a minimum every hour, between shifts and if station areas become visibly soiled. Incorporate other <a href="CDC/EPA guidance">CDC/EPA guidance</a> as appropriate for your clinic circumstances.
- 7. Ensure staff is wearing appropriate PPE.



- 8. Ensure supplies such as tissues, hand sanitizer, and wastebaskets are readily accessible throughout the clinic.
- 9. Hand hygiene must be performed between patients. If gloves are worn by those administering vaccine, they should be changed, and hand hygiene should be performed between patients.
- 10. Make sure there are signs, barriers, and floor markers throughout the clinic to instruct patients to maintain a 6-foot distance from others and promote use of hand hygiene, respiratory hygiene, and cough etiquette.
- 11. Provide extra cleaning and sanitizing support. Frequently clean and disinfect all patient service counters and patient contact areas, including frequently touched objects and surfaces, such as workstations, keyboards, telephones, and doorknobs.
- 12. Ensure staff is wearing identification cards or other identification (vests, shirts, etc.), as appropriate.
- 13. Communicate clinic updates and wait times.
- 14. Have a plan in place for using ALL doses available in open vials, even if all appointments are completed for the day. Vaccine doses should not be wasted. Consider having a list of individuals who were not able to make an appointment, and call them if additional doses are available. It is more important to use all available doses than to strictly adhere to individuals who meet the current phase.

## c. Staffing

- 1. Establish a staffing plan and identify functional roles and responsibilities for each clinic. More guidelines on administrative and clinical staffing from the CDC can be found <a href="here">here</a>.
- 2. Ensure staff is properly trained to administer vaccine. VDH resources can be found <a href="here">here</a>. CDC COVID-19 Vaccine Training Modules can be found <a href="here">here</a>.
- 3. Additional staff may be needed to:
  - a. Help enforce physical distancing measures.
  - b. Clean the facility frequently.
  - c. Provide IT support for online processes, including registration, scheduling, screening for eligibility, contraindications, and precautions, obtaining insurance information, providing vaccine information statements or emergency use authorization (EUA) forms, etc.



## d. Supplies & Materials

- 1. Leverage the Satellite, Temporary, and Off-Site Vaccination Clinic Supply Checklist
- 2. During the COVID-19 pandemic, protection must be available for staff and patients. <u>Supplies</u> required during the COVID-19 pandemic include:
  - a. Alcohol-based hand sanitizer with at least 60% alcohol and hand soap
  - b. Cleaning supplies for more frequent cleanings, using <u>EPA's Registered Antimicrobial Products for Use Against Novel Coronavirus SARS-CoV-2</u>
  - c. Masks for patients who arrive without one
  - d. <u>Personal protective equipment (PPE)</u> for staff, including face masks, gloves, and eye protection, based on <u>current guidance for the safe delivery of vaccination services</u>
  - e. Thermometers for checking patients' temperatures before they enter the clinic, if required
  - f. Tissues
- 3. Ancillary kits for Moderna vaccine will contain supplies to administer **100 doses**. The Pfizer-BioNTech ancillary kit will contain supplies to administer **975 doses**. Ancillary kits will contain needles (22-25G x 1" and 22-25G x 1.5"), syringes, alcohol pads, vaccination record cards, needle gauge and length chart, face shields, and surgical masks, and diluent vials (for Pfizer-BioNTech only).
- 4. Ancillary supply kits **will not include** sharps containers, gloves, and bandages. Additional personal protective equipment may be needed depending on vaccination provider site needs.
- 5. Use 3mL syringes for optimal performance when mixing Pfizer-BioNTech vaccine.
- 6. Anaphylaxis after vaccination is rare, but can occur. It is mandatory that all vaccination providers have supplies immediately available to address acute anaphylactic reactions. To appropriately monitor and attend to any allergic reaction to the vaccine, all vaccine providers should have the following supplies available to assess and treat anaphylaxis: epinephrine (first drug of choice), H1 antihistamine (may be given as adjunctive treatment but should not be used as initial or sole treatment for anaphylaxis), blood pressure cuff, stethoscope, and a timing device to assess pulse. More information from the CDC about preparing for the potential management of anaphylaxis after COVID-19 vaccination can be found here. Each health district should have a well developed plan for addressing anaphylaxis. Yearly emergency procedures drills are mandatory for all staff. A minimum of three doses of epinephrine must be available at each clinical site. Consider requesting EMS personnel to assist with monitoring for post vaccination anaphylaxis.



#### II. Pre-Vaccination Patient Intake & Education

1. Spend time educating staff about the vaccine. Guidance on patient counseling can be found in the CDC Clinical Considerations.

#### 2. **Before** administering the vaccine:

- a. Screen patients for acute SARS-CoV-2 infection and defer those with current infection from vaccination until they have recovered and have met the criteria to discontinue isolation.
- b. Explain to patients this is a two-shot series and they will need to return if this is their first shot (after 21 days for Pfizer-BioNTech COVID-19 vaccine and after 28 days for the Moderna COVID-19 vaccine).
- c. Provide <u>EUA fact sheets</u> to every patient. Verify the patient/parent/caregiver receives the fact sheet, has time to read information and ask questions, and has an opportunity to discuss side effects.
- d. Screen all recipients for contraindications and precautions. Review for appropriate vaccination or deferral. Refer to <u>Appendix A</u> for the triage form from CDC.
  - i. Persons who have had a severe allergic reaction to a first dose of a COVID-19 vaccine should **not** receive the second dose.
  - ii. Refer to the <u>CDC Clinical Considerations</u> for guidance for vaccinating patients who are pregnant or have underlying medical conditions.
- e. Capture date of birth.
- f. Ensure patients are ≥16 years if receiving the Pfizer-BioNTech vaccine or ≥18 years if receiving the Moderna vaccine.

# III. Vaccine Storage & Handling

- 1. Ensure plans are in place for maintaining vaccine at appropriate temperatures while stored and throughout the clinic day based on <u>vaccine storage and handling guidance</u>. Monitor and document vaccine temperatures as required throughout the day.
- 2. CDC's <u>Vaccine Storage and Handling Toolkit</u> provides guidance on safe and effective vaccine management practices for all healthcare providers.
- 3. A contingency plan should also be in place, in case vaccines are delayed or compromised and need to be replaced.
- 4. Finalize your plan for administering the second dose before the initial doses are administered.



# IV. Vaccine Preparation & Administration

# a. Vaccine Preparation

- 1. Vaccines must be thawed prior to mixing (Pfizer-BioNTech) or administration.
  - a. Pfizer-BioNTech: Thaw at room temperature between 30 minutes and 2 hours before mixing.
  - b. Moderna: Thaw at room temperature (59 to 77 °F) for 1 hour **or** in refrigerated conditions between (36 to 46 °F) for 2 hours and 30 minutes then at room temperature for 15 minutes.
- 2. Dilution required using 0.9% Sodium Chloride for Pfizer-BioNTech vaccine.
- 3. **Do not dilute** Moderna vaccine.
- 4. **Do not shake** vaccine vials.
  - a. Pfizer-BioNTech: Gently invert and evert vials ten times to mix.
  - b. Moderna: Swirl vial gently after thawing and between each withdrawal. **Do not** use and contact the manufacturer if vials are shaken instead of swirled.
- 5. For Moderna vaccine, all doses will need to be used within 6 hours of opening a vial
- 6. For Pfizer-BioNTech vaccine, all doses must be used within 6 hours of dilution.
- 7. Do not re-freeze thawed vials.
- 8. Vaccines are not interchangeable. A patient must receive the second dose using the same vaccine used for the first dose. For example, if Moderna was used for the first dose, it must be used for the second; you cannot use the Pfizer-BioNTech vaccine for the second dose.

#### b. Vaccine Administration

- a. Vaccine must be administered Intramuscularly (IM) in the deltoid muscle. Take care to avoid shoulder injury. Pinching the skin, which is recommended for subcutaneous injections, should not be performed for IM injections.
- b. Follow the "seven rights" of vaccine administration: right patient, right vaccine/diluent, right time, right dose, right route, right site, and right documentation.



#### V. Post Vaccination

- 1. Ensure patients know that CDC has recommended that no other vaccines be given 2 weeks before or after a COVID-19 vaccine. This means if they just received their first COVID-19 vaccine, they should not get any other vaccines until they receive their second COVID-19 vaccine. If this is their second COVID-19 vaccine, they cannot get another vaccine for 2 weeks.
- 2. Provide all patients with:
  - a. Details on how to sign up for v-safe. Leverage this <u>handout</u>.
  - b. Details for signing up for VaxText. Leverage this handout.
  - c. A filled in second dose card including a scheduled follow up appointment. Persons should not be scheduled to receive the second dose earlier than recommended (i.e., 21 days [Pfizer-BioNTech] or 28 days [Moderna]). However, second doses administered within a grace period of 4 days earlier than the recommended date for the second dose are still considered valid. Doses inadvertently administered earlier than the grace period do not need to be repeated. There is no maximum interval between the first and second doses for either vaccine. Therefore, if the second dose is administered >21 days after the first Pfizer-BioNTech vaccine dose or >28 days after the first Moderna vaccine dose, there is no need to restart the series. Vaccine administration errors should be reported to the Vaccine Adverse Event Reporting System (VAERS).
- 3. People who have been vaccinated must be wearing masks and **distanced at a minimum of 6 feet apart in a well-ventilated indoor or outdoor space in the direct sight line of an observer**. Persons with
  a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy and
  persons with a history of anaphylaxis due to any cause should be observed for **30 minutes**. Others
  should be observed for **15** minutes. Staff should be prepared to respond to any immediate reactions
  that occur during the observation period.
  - a. Ensure all patients are wearing a mask throughout the observation period.
  - b. Choose an area with no foot or vehicle traffic.
  - c. Adhere to 6 feet physical distancing.
  - d. Ensure people feel safe and comfortable.
  - e. Consider giving each recipient a timer to track their 15 minutes, then clean the timers and reuse them.
- 4. You are required to report the following to VAERS:



- a. Vaccine administration errors (whether associated with an adverse event [AE] or not)
- b. <u>Serious AEs</u> (irrespective of attribution to vaccination)
- c. Multisystem inflammatory syndrome (MIS)
- d. Cases of COVID-19 that result in hospitalization or death after the recipient has received COVID-19 vaccine
- 5. You are encouraged to report any clinically significant AEs that occur after vaccine administration.
- 6. Adverse events should be reported even if the cause of the AE is uncertain.
- 7. Immediately treat suspected cases of anaphylaxis with intramuscular injection of epinephrine. More information from the CDC about preparing for the potential management of anaphylaxis after COVID-19 vaccination can be found <a href="here">here</a>.

# VI. Record Keeping

- 1. Fully document vaccine in patient chart: date, lot number, expiration, manufacturer, injection site, vaccinator, EUA vaccine fact sheet date.
- 2. It is essential to track the lot numbers of the vaccines in case of adverse reactions.
- 3. Have a copier nearby in case you need to duplicate cards, paperwork, etc.
- 4. Attend an updated VIIS training.
- 5. Ensure you have maintained required documentation from the Board of Pharmacy.



# Appendix A: Triage of persons presenting for mRNA COVID-19 vaccination

	MAY PROCEED WITH VACCINATION	PRECAUTION TO VACCINATION	CONTRAINDICATION TO VACCINATION
CONDITIONS	CONDITIONS  Immunocompromising conditions Pregnancy Lactation  ACTIONS Additional information provided* Is minute observation period	CONDITIONS  Moderate/severe acute illness  ACTIONS  Risk assessment Potential deferral of vaccination  15-minute observation period if vaccinated	CONDITIONS  None  ACTIONS  N/A
ALLERGIES	ALLERGIES  History of allergies that are unrelated to components of an mRNA COVID-19 vaccine <sup>†</sup> , other vaccines, injectable therapies, or polysorbate, such as:  Allergy to oral medications (including the oral equivalent of an injectable medication)  History of food, pet, insect, venom, environmental, latex, etc., allergies  Family history of allergies  ACTIONS	ALLERGIES  History of any immediate allergic reaction* to vaccines or injectable therapies (except those related to component of mRNA COVID-19 vaccines* or polysorbate, as these are contraindicated)  ACTIONS:	ALLERGIES History of the following are contraindications to receiving either of the mRNA COVID-19 vaccines†:  Severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or any of its components  Immediate allergic reaction‡ of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components (including polyethylene glycol)#  Immediate allergic reaction of any severity to polysorbate^#
	30-minute observation period: Persons with a history of anaphylaxis (due to any cause)     15-minute observation period: All other persons	<ul> <li>Risk assessment</li> <li>Consider deferral of vaccination and/or referral to allergistimmunologist</li> <li>30-minute observation period if vaccinated</li> </ul>	ACTIONS  Do not vaccinate#  Consider referral to allergist-immunologist

Source: CDC. Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States (last updated January 6, 2021). Available at <a href="https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html">https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html</a>. Additional information on COVID-19 vaccination and and testing, including tuberculosis testing, can be found in this document.

\*See Special Populations section for information on patient counseling in these groups

† Refers only to mRNA COVID-19 vaccines currently authorized in the United States (i.e., Pfizer-BioNTech, Moderna COVID-19 vaccines)

‡ Immediate allergic reaction to a vaccine or medication is defined as any hypersensitivity-related signs or symptoms consistent with urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration.

^ See Appendix B for a list of ingredients. Note: Polyethylene glycol (PEG), an ingredient in both mRNA COVID-19 vaccines, is structurally related to polysorbate and cross-reactive hypersensitivity between these compounds may occur. Information on ingredients of a vaccine or medication (including PEG, a PEG derivative, or polysorbates) can be found in the package insert.

# These persons should not receive mRNA COVID-19 vaccination at this time unless they have been evaluated by an allergist-immunologist and it is determined that the person can safely receive the vaccine (e.g., under observation, in a setting with advanced medical care available)



# **Appendix B: Resources & References**

- 1. Guidance for Planning Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations: <a href="https://www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/index.html">https://www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/index.html</a>
- 2. Nursing directive: Emergency Treatment of Anaphylaxis (2020): <a href="https://vdhweb.vdh.virginia.gov/nursing/directives-guidelines/">https://vdhweb.vdh.virginia.gov/nursing/directives-guidelines/</a>
- 3. VDH COVID-19 Vaccination Response Resources for Healthcare Professionals: <a href="https://www.vdh.virginia.gov/covid-19-vaccine/healthcare-professionals/">https://www.vdh.virginia.gov/covid-19-vaccine/healthcare-professionals/</a>

